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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,147	02/25/2002	Peng Cho Tang	038602-1329	1170

22428 7590 06/18/2003

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

10

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/081,147

Applicant(s)

TANG ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,9-16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☒ Claim(s) 1-5,9-16 and 18-22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

This action is in response to Applicant's amendment filed 4-20-03. Claims 1, 4, and 5 have been amended. Claims 1-5, 9-16, and 18-22 are pending in this application.

The objection to claims containing nonelected subject matter has been maintained. The double patenting rejection has been withdrawn. Process claims 16 and 18-22 have been rejoined.

### ***Election/Restrictions***

The following generic concept as depicted in claim 1 is identified for examination along with the elected embodiment: R<sup>9</sup> is alkyl substituted with substituted or unsubstituted nitrogen; R3 and R4, and R4 and R5 do not combine to form a ring, and all other variables are as defined. The remaining subject matter of claims 1-5, 9-12, 15 in part and claims 13 and 14 in their entirety is withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

Claims 1-5, and 9-12 in part are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to wherein R3 and R4, and R4 and R5 do not combine to form a ring.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

#### Nature of the Invention

Claim 16 is directed to "preventing a protein kinase related disorder."

#### State of Prior Art

The prior arts do not indicate that the instant compound is capable of "preventing all protein kinase related disorders.

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Level of Ordinary Skill in the Art

There are a vast number of protein kinase related disorders and Applicant does not give support for "preventing" all protein kinase disorders.

Level of Predictability in the Art

The various types of protein kinase related disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. The protein kinase related disorder therapy art, such as the cancer therapy art, remains highly unpredictable.

Amount of Direction and Guidance Provided by the Inventor

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It has not been shown in the specification that the testing protocol used is accepted in the art as being predictive of the alleged utility. In vitro tests or tests using animal models by themselves do not establish the usefulness of an invention absent art-recognized correlation between such test and the ultimate use. Merely identifying substances as objects for further use--testing (speculative utility)--is insufficient to provide an enabling disclosure.

Existence of Working Examples

Applicant provides limited examples which do not support that the instant compound can be used in "preventing" protein kinase disorders.

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Breadth of Claims

Claim 16 is extremely broad because there are a large number of protein kinase disorders.

Quantity of Experimentation Needed to Make or Use the Invention Based on the

Content of the Disclosure

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

It is suggested that applicants delete "preventing" from claim 16 in order to obviate the rejection under 35 U.S.C. 112 first paragraph.

***Claim Objections***

Claims 15 and 18-22 are objected to as being dependent upon a rejected base claim.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive with respect to the objection to claims containing non-elected subject matter. Applicant argues that claim 1 has been amended to recite the subject matter that the Examiner has considered.

Applicant has amended the claims to recite that R9 is alkyl substituted with substituted or unsubstituted nitrogen, however, Applicant has not amended the claims to recite that R3 and R4, and R4 and R5 do not combine to form a ring.

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Applicant's arguments have been found persuasive with respect to the rejoinder of process claims. Therefore, process claims 16 and 18-22 are rejoined. It is requested that Applicant delete "preventing in process claim 16 to overcome the rejection under 35 U.S.C.112 first paragraph, supra.

Applicant will note that deleting "preventing" will make instant process claim 16 consistent with process claims 5 and 6 in the parent, Serial Number 09/322,297, now allowed, US Patent 6,395,734.

Process claims 13 and 14 have not been rejoined because they are not free of 112 issues.

The references which the Examiner did not have copies of in the instant application or in the parent, application number 09/322,297, have been lined through.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for

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draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

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Joseph K. McKane

Supervisory Patent Examiner

Group 1600

*Alan L. Rotman*

ALAN L. ROTMAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Sonya Wright

June 11, 2003